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Strengthening HIV Test Access and Treatment Uptake Study (Project STATUS): A Randomized Trial of HIV Testing and Counseling Interventions

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Abstract

Objective—To determine which of 3 HIV testing and counseling (HTC) models in outpatient departments (OPDs) increases HIV testing and entry of newly identified HIV-infected patients into care.

Design—Randomized trial of HTC interventions.

Methods—Thirty-six OPDs in South Africa, Tanzania, and Uganda were randomly assigned to 3 different HTC models: (A) health care providers referred eligible patients (aged 18–49, not tested in the past year, not known HIV positive) to on-site voluntary counseling and testing for HTC offered and provided by voluntary counseling and testing counselors after clinical consultation; (B) health care providers offered and provided HTC to eligible patients during clinical consultation; and (C) nurse or lay counselors offered and provided HTC to eligible patients before clinical consultation. Data were collected from October 2011 to September 2012. We describe testing eligibility and acceptance, HIV prevalence, and referral and entry into care. Chi-square analyses were conducted to examine differences by model.

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A.D.M. and A.S.M. wrote the article; J.S. conducted the analyses; T.F., N.W., M.N., N.M.-R., S.M., and A.A. were involved in implementation; and J.M. was involved in the conception and design of Project STATUS. All authors commented on drafts of the article.

Results—Of 79,910 patients, 45% were age eligible and 16,099 (45%) age eligibles were tested. Ten percent tested HIV positive. Significant differences were found in percent tested by model. The proportion of age eligible patients tested by Project STATUS was highest for model C (54.1%, 95% confidence interval [CI]: 42.4 to 65.9), followed by model A (41.7%, 95% CI: 30.7 to 52.8), and then model B (33.9%, 95% CI: 25.7 to 42.1). Of the 1596 newly identified HIV positive patients, 94% were referred to care (96.1% in model A, 94.7% in model B, and 94.9% in model C), and 58% entered on-site care (74.4% in model A, 54.8% in model B, and 55.6% in model C) with no significant differences in referrals or care entry by model.

Conclusions—Model C resulted in the highest proportion of all age-eligible patients receiving a test. Although 94% of STATUS patients with a positive test result were referred to care, only 58% entered care. We found no differences in patients entering care by HTC model. Routine HTC in OPDs is acceptable to patients and effective for identifying HIV-infected persons, but additional efforts are needed to increase entry to care.

Keywords

counseling/methods; HIV infections/diagnosis; sero-prevalence; South Africa; Tanzania; Uganda

INTRODUCTION

HIV testing and counseling (HTC) is an important entry point to HIV prevention, care, and treatment, and an integral component of efforts to achieve universal access to HIV services. Identifying HIV positive persons and linking them to care and treatment can improve health outcomes[1–5] and decrease HIV transmission through viral load suppression.[5,6]

To improve access to HIV prevention, care, and treatment services in developing countries, the World Health Organization and the Joint United Nations Programme on HIV/AIDS published guidance in 2007 calling for the scale-up of HTC in health facilities worldwide.[7,8] For countries with generalized HIV epidemics, this guidance recommends that in addition to client-initiated HTC, health care providers should recommend HTC as part of routine care, regardless of whether the patient shows signs and symptoms of HIV infection, or their reason for attending the health facility.[7] More than 42 countries have adopted policies on HIV testing in a variety of health care settings including inpatient and outpatient departments (OPDs), antenatal care (ANC) and tuberculosis (TB) clinics, and emergency and surgical departments.[9]

Routine HTC is being successfully implemented in inpatient wards and in TB, sexually transmitted infection, and ANC clinics in many countries. Among countries receiving financial and technical assistance through the President's Emergency Plan for AIDS Relief, HIV testing in some ANC clinics has exceeded 50% of attendees, with some testing more than 80%.[10,11] HIV testing in TB clinics has also increased, reaching over 50% of patients in several countries.[12] A review of studies of HTC implementation in clinical settings reports even higher levels of testing under controlled study conditions.[13] These successes indicate that in appropriately resourced contexts, implementation of routine HTC is achievable.

Several studies have reported feasibility and uptake of HIV testing in OPDs, showing that testing in OPDs is achievable,[14–16] but rates of testing are relatively low compared with other clinical venues.[13] As a primary source of health care for many people in developing countries, OPDs provide a venue for accessing large numbers of people from the general population. Although we do not know how many people accessing OPDs know their HIV status, OPDs may offer the opportunity to efficiently diagnose many infected persons before they develop life-threatening illness. Assessing the outcomes of HIV testing in OPDs would provide valuable information about the importance and feasibility of HIV testing in this setting and could inform policy-makers about how and why various HTC models may or may not be effective. Furthermore, determining whether different models of HTC delivery in the OPD vary in the number of HIV infected persons identified and linked to care and treatment services would be valuable information for decision makers trying to stretch HTC resources while assuring the greatest public health impact.

We present the findings of Project STATUS, a randomized trial of HTC interventions in OPDs in primary health care centers and district-level hospitals in South Africa, Tanzania, and Uganda. The primary objective of this evaluation was to compare 3 models of HTC in OPDs to determine which model results in the highest percentage of eligible outpatients receiving an HIV test and the highest percentage of HIV infected persons newly identified in the OPD who enter HIV care and treatment services.

METHODS

Study Design

Thirty-six OPDs in South Africa, Tanzania, and Uganda participated in Project STATUS. Each country selected a convenience sample of 12 OPDs in primary health care centers or district-level hospitals for inclusion in the study. Facilities varied in the size of their patient population but were comparable in the services offered and met the following inclusion criteria: OPD located at a district-level hospital or health care center in which less than 5% of outpatients were receiving routine HTC; provider-to-patient ratio of 1 health care provider providing care to 25–35 patients per day; on-site voluntary counseling and testing (VCT) center or services; space to conduct private HTC sessions; provision of HIV care and treatment services at the health facility; and ability to determine CD4 T-lymphocyte counts on-site or by sending blood samples to an off-site laboratory. Block randomization was used to assign the 12 OPDs in each country to one of 3 HTC models, resulting in 4 OPDs per model in each country or 12 OPDs per model across all 3 countries. Institutional review boards at the Centers for Disease Control and Prevention and in each country approved the study protocol.

In addition, patient interviews were conducted at all participating OPDs, 2 randomly selected OPDs per model per country conducted a time motion study, and 1 conveniently selected OPD per model per country participated in provider focus group discussions after the data collection period. These data are not reported in this article.

Data Collection

At each participating health facility, health care providers, HTC nurse or lay counselors, and other relevant persons in the OPD were trained to deliver the HTC model to which their facility was randomized. Providers were trained on data collection procedures and the use of data collection tools. After a 2-month pilot study, data collection for HTC and HIV care entry was conducted for a 3-month study period (between October 2011 and September 2012). STATUS participants who entered HIV care were followed for 4 months after care entry to determine whether they returned to care.

HIV Testing and Counseling—All patients attending a STATUS OPD during the study period were registered in a study log, in which age and sex were documented, and a unique study identifier was assigned. All OPD patients were given a packet containing a patient enumeration form (PEF) and referral cards, all marked with the patient's unique study identifier (PEF number). Study staff documented patients' age and sex on the PEF and requested that patients carry the packet with them throughout their visit. Patients in all models were eligible for HTC as part of Project STATUS if they were

- attending the OPD for a consultation with a health care provider for any routine or acute medical condition (excluding emergency cases),
- age eligible (18–49 years),
- test eligible (no documentation in patient records of having an HIV test in the past year or of ever testing HIV positive),
- able to provide informed consent for HIV testing.

The age of 18 was selected as the lower limit for study eligibility because it is the age of majority in the 3 participating countries; thus, patients 18 and older could legally provide verbal consent for HIV testing. The upper limit of 49 was selected to target persons at risk for HIV infection. OPDs typically see a high percentage of older patients, particularly the elderly, who would likely be at lower risk for HIV infection.

STATUS participants who tested HIV positive in all models were given a Project STATUS Care and Treatment Referral Card and encouraged to access on-site HIV care. The 3 HTC models are described below.

Model A: Health care providers referred eligible patients to on-site VCT services *after* clinical consultation. For age eligible patients, test eligibility was determined by the health care provider during the consultation. Test eligibility and referral to VCT were documented on the PEF by the provider, who referred test-eligible patients to VCT at the end of the consultation. For patients who went to VCT after their consultation, the VCT counselor documented whether they offered the patient HTC, whether they tested the patient, and the result. Patients testing HIV positive were referred to onsite HIV care by the VCT counselor, who also recorded referral data on the PEF.

Model B: All OPD patients in the waiting area heard a group talk that included HIV information. Eligible patients were offered HTC *during* clinical consultation. Test eligibility

of age eligible patients was determined by the health care provider, who also recommended and provided HTC during the consultation. The provider referred HIV positive patients to on-site HIV care and documented all testing and referral data on the PEF.

Model C: Eligible patients were offered and provided HTC *before* clinical consultation. Age eligible patients were sent to a waiting area separate from non–age eligible patients, where the age eligible patients heard a group talk about HIV. These patients were encouraged to be tested for HIV by a nurse or lay counselor before their clinical consultation and assured they would not lose their place in the queue to see the provider. Patients who chose to see the counselor had test eligibility determined by the counselor and were offered and provided HTC by the counselor before their consultation. Persons who tested HIV positive were informed of their result by the counselor, who documented all eligibility and testing data on the PEF. The OPD provider reviewed patients' PEFs during the clinical consultation and referred HIV positive patients to on-site HIV care after the consultation. The provider documented referral data on the PEF.

OPD patients who did not meet STATUS age or test eligibility criteria, but wanted to receive a test, were provided testing; testing and referral data for these patients were not documented on their PEFs.

Entry Into HIV Care—Each model included referring all patients who tested HIV positive to on-site HIV care. Entry into HIV care was defined as having the patient's information documented in the facility's HIV care and treatment register and/or patient's medical record. Project STATUS Care and Treatment Referral Cards included a peel-off sticker printed with the patient's PEF number, which was affixed in the HIV care and treatment register to identify STATUS patients. Study staff were not able to assess care entry at non-STATUS HIV care and treatment facilities.

Analyses

We describe a cascade including age eligibility, test eligibility, receipt of HIV test, HIV prevalence, and referral to and entry into HIV care, in which each step in the cascade is dependent on the previous step. Rao Scott modified χ^2 tests were conducted to examine differences by model for HIV test eligibility, testing rates, referral, and care entry. Analyses were conducted using SAS version 9.3.2 (SAS Institute, Cary, NC). All analyses, both descriptive and inferential, accounted for the study design by including the clustering within facility and stratification by country in the estimation of variances and 95% confidence intervals. In addition, because random selection of patients was not possible and the number of patients attending each OPD varied, there were unequal sampling rates across OPDs; therefore, sampling weights were used. These weights were created using the population size of the OPD during the study, the number of participants eligible for each outcome, and the number sampled. Therefore, different weights were used for estimating each outcome.

RESULTS

Test Eligibility and Outcomes Among All OPD Attendees

During the 3-month study period, a total of 79,910 patients were registered in the 36 study OPDs. Forty-five percent of registered patients were age eligible, with a mean age of 29 years. Seventy-four percent of age eligible patients were women. Sixty-one percent (n = 22,034) of age eligible patients were determined to be test eligible (62% of all age-eligible women and 73% of all age eligible men). Providers determined 9987 age eligible patients were ineligible for testing; 6320 had documentation of a nonreactive test in the past 12 months; and 3605 had documentation of a previous reactive test (patients could have both documentation of a nonreactive test in the past 12 months and of a previous reactive test). Of the age eligible patients, 16,132 (45%) were tested with an overall prevalence of 10% (women 10.0% and men 9.5%). HIV prevalence for STATUS patients was higher in South Africa (22%) than in Tanzania and Uganda (6% each). Ninety-four percent of the 1596 newly diagnosed HIV-positive patients from the OPD were referred to HIV care, and fifty-eight percent (n = 932) of those referred had documentation of registering at the on-site care and treatment clinic. We identified an additional 23 STATUS patients with documentation of entering care but no documentation of being referred to care.

Cascade of Testing Uptake, Referral to Care, and Care Entry by Model

In model A, 6564 (67%) age eligible participants were determined by the OPD provider to be test eligible during the clinical consultation (Fig. 1A). Eighty-three percent (n = 5448) of the 6564 eligible patients were referred to VCT, and 84% of all eligible patients actually went to VCT. Of those who went to VCT, 99% were offered testing, and 93% of patients offered testing accepted. Of the 445 persons who tested HIV positive, 95% were referred to care, and 75% of those who were referred entered care.

In model B, 57% of the age eligible participants were determined by the OPD provider to be test eligible during the clinical consultation (Fig. 1B). Model B providers indicated that they offered testing to 99% of test-eligible patients, and 65% accepted. Of the 520 persons who tested HIV positive, 94% were referred to care, and 57% of those who were referred entered care.

In model C, 9004 (80%) age eligible patients went to the HTC counselor before their clinical consultation (Fig. 1C). Seventy-eight percent were determined by the counselor to be test eligible, 99% of test-eligible patients were offered testing, and 92% accepted. Of the 631 persons who tested HIV positive, 94% were referred to care, and 57% of those who were referred entered care.

Differences in Testing Rates, Referrals, and Care Entry by Model

No significant differences were found among models in the percentage of total patients attending the OPD or the percentage of patients who were age eligible or test eligible (Table 1). When we examined the percentage of patients who were tested in the OPD among those who were age eligible, we found a significant difference by model (Table 2). The proportion of all age eligible patients who were tested was highest for model C (54.1%), followed by

model A (41.7%), and then model B (33.9%). When we examined the percentage of patients tested among those determined to be test eligible, we also found a significant difference by model with higher testing rates in model A (93.0%) and model C (91.9%) than in model B (65.5%) (Table 1). There were no significant differences by model in the percentage of patients found to be HIV positive or in the percentage of patients referred to care (96.1% in model A, 94.7% in model B, and 94.9% in model C). The percentage of referred patients who entered care was highest for model A (74.4%) compared with model B (54.8%) and model C (55.6%); however, this finding was not statistically significant. An additional analysis was conducted including those patients who entered care without documentation of referral, which also found no significant difference in care entry by model (data not shown).

DISCUSSION

Implementing HTC as Standard of Care

Despite World Health Organization's recommendation that HTC be offered as a standard part of medical care in countries with generalized HIV epidemics[7] and an increase in the implementation of HIV testing in sub-Saharan Africa (SSA),[11,17] nationwide routine HTC in OPDs is still not a common practice. The benefits of implementing a policy of routine opt-out HIV testing in SSA, including the potential for earlier antiretroviral therapy initiation and ultimately increased survival of persons with HIV, must be considered alongside the possible drawbacks of this approach such as patients thinking they cannot refuse or the stigma associated with a positive test result.[18–21] Project STATUS demonstrated that it is feasible to routinely offer HTC to OPD patients and have substantial testing uptake, identify many undiagnosed HIV-infected persons, and have a substantial proportion enter HIV care soon after diagnosis.

Testing Uptake

STATUS resulted in high testing uptake with more than 81% of all persons offered testing accepting a test (16,132/19,953). Other studies have shown that routine HIV testing in health care settings is acceptable to patients and an effective method for increasing HTC uptake.[15,22–24] For example, a study conducted in Zambian primary care clinics reported that 75% of patients with no proof of their HIV status who were offered HTC accepted under a model C–type arrangement.[15]

Patients were lost at different points in the cascade of each model. In model A, 16% of patients were never referred to VCT by the OPD provider, and not all who were referred went. Of those who went to VCT, 93% were tested. In model B, almost all test-eligible patients were offered HTC, but 35% declined. In model C, similar to model A, 20% of patients chose not to go to the area of the OPD where HTC was being offered, thereby essentially "opting out." Of those who went, 92% were tested.

Given that patients in model C who "opted out" by not going to testing did not have their test eligibility determined, we compared testing rates by model among all age eligible patients rather than just test-eligible patients. The percentage of age eligible patients receiving a test was highest in model C. There are several possible reasons for this finding.

Model C OPDs had a separate waiting area for HTC located near the main waiting area and close to where testing was provided, allowing patients to conveniently test before their OPD consultation without worrying about losing their place in the queue to see the provider. Model C had designated staff trained and tasked to provide HTC, making the process quick. Unlike model A, there was no additional waiting time to receive HTC in model C; the waiting time to see the nurse or lay counselor for testing occurred during, not in addition to, the waiting time to see the OPD health care provider. Age eligible patients in model C OPDs also received a health talk from the OPD staff reinforcing the importance of knowing their HIV status and informing them that HIV care was available on-site for anyone with a positive result. Although model C resulted in the highest testing uptake, it also required substantial changes to OPDs' standard operating procedures. Countries and OPDs considering implementation of this model must consider how changes to patient flow can be operationalized and how the additional staff needed to provide HTC before the OPD consultation can be effectively integrated.

The various methods currently being used in SSA have both strengths and limitations. Before the recommendation that health care providers routinely offer testing to all patients,[7] the most common practice in OPDs was provider referral to a VCT site within the health facility, similar to STATUS' model A. This model is successful at identifying persons with HIV, as patients who perceive themselves to be at risk may be more motivated to test. However, those who perceive themselves to be at low risk may choose not to access VCT or to accept a test. Others may choose not to access services at the VCT because of the additional time required. In addition, previous studies have shown that uptake of HTC in a model A–type arrangement is lower among those experiencing poverty,[25] who fear or have experienced stigma and discrimination,[25,26] and who have lower education levels.[27] STATUS' model B was modeled after the diagnostic testing approach used in some OPDs, in which health care providers offer and provide HTC during the clinical consultation to patients suspected of having HIV. Although implementing this model routinely can result in a high proportion of patients offered and receiving testing, its success depends largely on the actions and attitudes of the provider. Rather than conducting routine HTC, the provider may use clinical judgment to determine who may be HIV infected or at risk, resulting in patients who are asymptomatic or whom the provider perceives as having no risk not receiving HTC.[7] A study by Dalal et al[16] involving provider-initiated testing and counseling (PITC) under a model B–type arrangement identified increased workload and concerns regarding confidentiality as concerns of providers delivering this model. It is possible that providers in Project STATUS OPDs assigned to model B did not actually offer all eligible patients HTC because of the increased workload, confidentiality concerns, or other reasons, but indicated on the PEF that HTC was offered and the patient declined. Other studies have reported success with testing strategies similar to STATUS' model C. A study in a South African OPD assessed a routine voluntary HIV testing intervention compared with the standard-of-care provider-referral to a VCT site located in the same hospital complex as the OPD. Offering pretest information and HIV testing while patients waited to see the provider, the routine HTC intervention resulted in a 10-fold increase in HIV tests completed and over 4 times as many HIV positive persons identified.[14] A Zambian study that introduced PITC delivered by lay counselors in 9 urban primary care facilities tested twice as many patients

than when conducting VCT alone.[15] The high acceptance of routine PITC in these studies and in Project STATUS may be due in-part to making HTC a standard feature of attending a health facility.[7,15]

Identification of HIV-Infected Persons, Referral to and Entry Into Care

Systematically offering HTC to all patients who visit the health facility increases the identification of HIV-infected patients.[14] In Project STATUS across all 3 countries, 10% of patients who tested were newly identified with HIV. HIV prevalence rates in the STATUS OPDs were similar to estimates reported for the same period in the areas where the STATUS OPDs were located in South Africa (22% versus 24.7% in KwaZulu-Natal Province)[28] and Uganda (6% versus 8.2% in Mid-Western Region).[29] In Tanzania, rates in the STATUS OPDs were higher (6% versus 3.2% and 2.4% in Arusha and Tanga regions, respectively).[30] Although HIV case finding rates are higher in other health care settings,[15,23,31] providing HTC in OPDs seems to be an effective method for identifying HIV positive individuals who are unaware of their status.

A goal of PITC is to link newly identified HIV-infected patients to care.[7] Although 94% of the 1596 newly HIV-diagnosed patients from Project STATUS were referred, only 58% of them entered care at the STATUS facility. Although not significant, the highest percentage entering care by model came from model A, in which VCT counselors referred patients to care.

Referral to and entry into care for patients with newly diagnosed HIV remains an issue.[32] A recent review of the operational implementation of PITC in SSA found linkage of newly identified HIV-infected patients to care was generally poor.[13] Given that HIV care is easier to access from OPDs than other testing venues, we would expect higher rates of linkage. STATUS patients may have accessed care at other facilities. Clearly, additional research is needed to understand linkage patterns and determine how to motivate patients or to offer them the support needed to access care.

Limitations

Our study had several limitations. Across all models, the performance of the model was dependent on participation by facility staff and fidelity to the assigned model, which varied by facility. Since documentation of previous HIV testing is generally limited, persons who had already been tested in the past 12 months may have been tested again as part of Project STATUS because previous testing was not documented. Estimates of care entry are likely conservative. As we followed a cascade of study activities, STATUS patients who were not documented as being referred to care were excluded from the care entry analysis. Patients who did not enter care the day diagnosed but returned at a later date may not have returned with their Care and Treatment Referral Card and therefore were not identified as STATUS patients in the care and treatment register. Data were not collected at non-STATUS facilities, so patients who entered care at a different facility were not documented.

Project STATUS demonstrated that routine HIV testing in OPDs is acceptable to patients and an effective method for identifying HIV-infected persons, but additional efforts are needed to increase entry to care. Model C, in which nurse or lay counselors offered and

provided HTC to eligible patients before their clinical consultation, had the highest percentage of all patients aged 18–49 years receiving a test. Model C was convenient; there was no additional waiting time to receive HTC, and HTC was provided by staff specifically trained and tasked to conduct HTC. This study demonstrates an important venue and model that could increase access to life-saving HIV-related services.

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APPENDIX 1. THE PROJECT STATUS STUDY TEAM

South Africa

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United States

Centers for Disease Control and Prevention, Atlanta, GA: Gillian Anderson, Stephanie Behel, Wei Fang, Jonathan Grund, Catherine Nichols, and Ray Ransom. ICF Macro: Sonal Pathak. US Agency for International Development, Washington, DC: Alison Surdo Cheng and Vincent Wong.

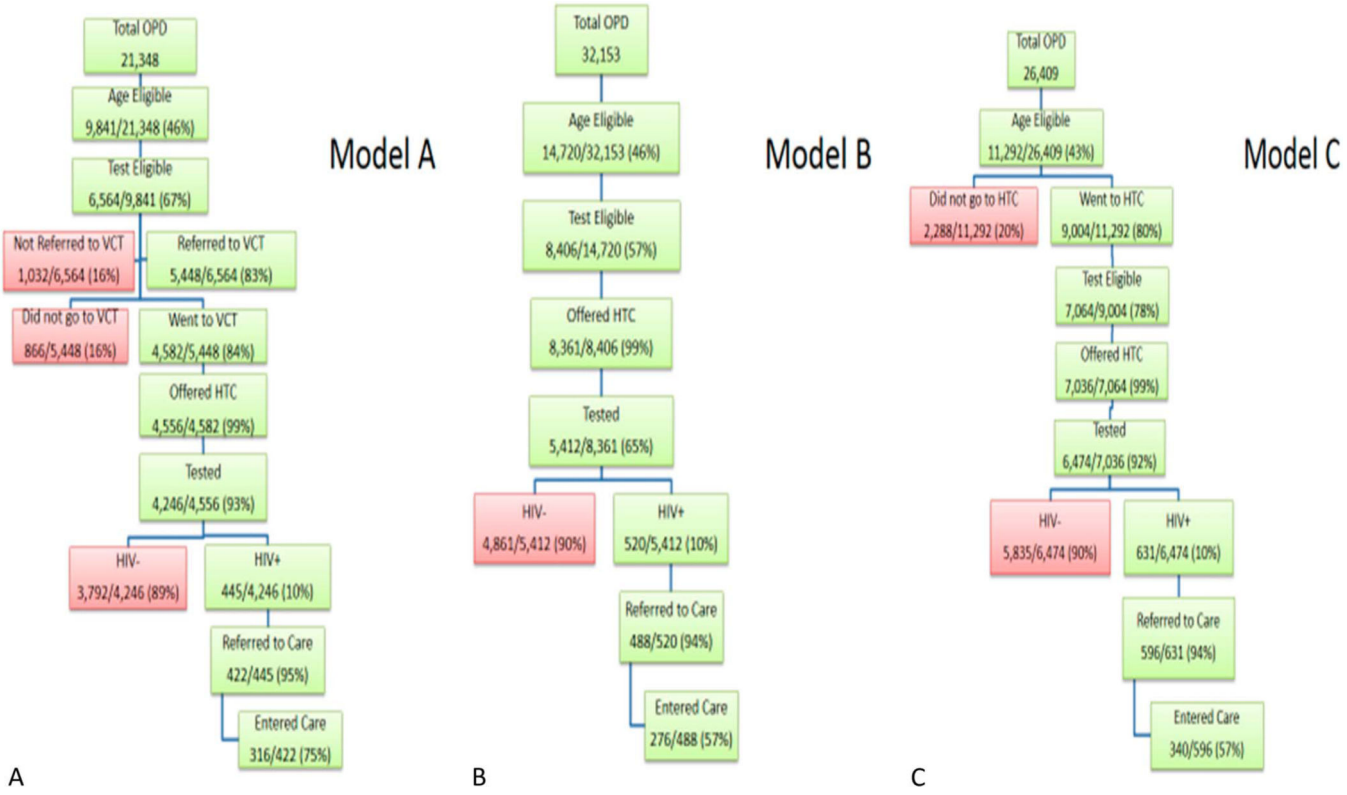

FIGURE 1.
Cascade of Testing Uptake, Referral to Care, and Care Entry by Model.

TABLE 1

Eligibility, Testing Rates, Identification of Patients with HIV, and Referral to and Entry Into Care by HTC Model Type, Project STATUS

	Model A		Model B		Model C	
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
Total OPD attendance	21,348	27.0 (9.8 to 44.2)	32,153	39.6 (18.0 to 61.2)	26,409	33.3 (13.2 to 53.4)
Age eligible	9841	43.2 (33.8 to 52.6)	14,720	45.9 (37.1 to 54.7)	11,292	42.5 (38.9 to 46.1)
Test eligible	6564	65.1 (54.4 to 75.8)	8406	55.6 (40.2 to 71.0)	7064	78.0 (69.9 to 86.1)
Test eligibles offered HTC	4556	99.4 (99.0 to 99.8)	8361	99.5 (99.3 to 99.8)	7036	99.6 (99.4 to 99.9)
Test eligibles offered HTC and accepted	4246	93.0 (90.2 to 95.8)	5412	65.5 (57.4 to 73.6)	6474	91.9 (87.2 to 96.6)
HIV positive	445	11.9 (6.2 to 17.7)	520	11.2 (7.3 to 15.0)	631	10.2 (7.0 to 13.3)
Referred to care	422	96.1 (92.7 to 99.6)	488	94.7 (91.9 to 97.4)	596	94.9 (92.8 to 97.0)
Entered care	316	74.4 (65.7 to 83.1)	276	54.8 (36.1 to 73.5)	340	55.6 (43.3 to 67.8)

TABLE 2

Percentage of All Age Eligible Patients Receiving HTC by Model, Project STATUS

	Model A		Model B		Model C		
	n	**% (95% CI)**	**n**	**% (95% CI)**	**n**	**% (95% CI)**	***P***
Total age eligibles tested	4246	41.7 (30.7 to 52.8)	5412	33.9 (25.7 to 42.1)	6474	54.1 (42.4 to 65.9)	0.0433